

IN THE CLAIMS:

This listing of claims replaces all prior versions and listings of claims in the application. Claims 4, 6-31, 34-39, 41-44, 46-48, 50-51, 53-55, 57-79, and 81-85 have been canceled without prejudice, claims 1, 5, 32, 40, 52, 56, and 80 have been amended, and new claims 86-175 have been added.

1. (currently amended) A [[flexible]] implantable brachytherapy treatment system, [[device, the device]] comprising
a therapy delivery portion comprising [[a]] at least one flexible non-dissolving casing and a support member or shielding enclosed within the casing; and
one or more radiation sources fixed relative to or received in the casing.

2. (original) The device of claim 1, further comprising an elongate removal portion extending from the therapy delivery portion.

3. (original) The device of claim 2, wherein the removal portion comprises an extension of the casing.

4. (canceled)

5. (currently amended) A removably implantable breast brachytherapy treatment system, [[device, the device]] comprising:

at least one non-dissolving tail portion; and

at least one therapy delivery portion, the therapy delivery portion comprising a flexible casing and one or more radiation sources fixed relative to the casing ~~a therapy delivery portion comprising a flexible casing and one or more radiation sources fixed relative to the casing; and~~
~~at least one non-dissolving tail portion extending from the therapy delivery portion.~~

6-31. (canceled)

32. (currently amended) A brachytherapy delivery apparatus, comprising:
means for simultaneously delivering [[implanting]], in a parallel array, a plurality of catheters into a target tissue region, wherein each catheter of the plurality of catheters is operable to receive one or more radioactive sources.

33. (original) A garment for attenuating radiation from an implantable brachytherapy device, the garment comprising:

a fabric portion operable to cover an area surrounding the brachytherapy device; and
a radiation attenuating material associated with the fabric portion.

34-39. (canceled)

40. (currently amended) A kit for delivering brachytherapy to a target tissue region of a body, the kit comprising:

a removably implantable elongate brachytherapy device comprising[[:]] a therapy delivery portion; and one or more low dose radiation (LDR) radioactive sources secured to the therapy delivery portion; [[and]]

at least one non-dissolving flexible tail portion [[extending from the therapy delivery portion]]; and

a catheter for delivering the brachytherapy device to the target tissue region.

41-44. (canceled)

45. (original) A catheter for implanting at least one radioactive source into a target tissue region of a body, the catheter comprising a radiotransparent portion and a radioabsorptive portion, wherein the radioabsorptive portion extends substantially along a longitudinal length of a dose delivery portion of the catheter.

46-48. (canceled)

49. (original) A catheter assembly for delivering one or more radioactive sources to a target tissue region of a body, the catheter assembly comprising:

a first catheter member; and

a second catheter member positionable within the first catheter member, the second catheter member operable to extend outwardly from an opening at or near a distal end of the first

catheter member such that an axis of the second catheter member intersects an axis of the first catheter member.

50-51. (canceled)

52. (currently amended) A catheter assembly for delivering a high dose [[radiation]] rate (HDR) radiation source to a target tissue region of a body, the catheter assembly comprising:

- a catheter shaft comprising a distal end and a proximal end;
- an inflatable balloon coupled to the catheter shaft between the distal end and the proximal end; and
- a dose delivery lumen extending along the catheter shaft between the proximal end and the distal end;

wherein a dose delivery portion of the catheter shaft coupled to [[surrounded by]] the inflatable balloon comprises a radioabsorptive portion.

53-55. (canceled)

56. (currently amended) A catheter assembly for delivering a high dose [[radiation]] rate (HDR) radiation source to a target tissue region of a body, the catheter assembly comprising:

- a catheter shaft comprising a distal end and a proximal end;
- an inflatable balloon coupled to the catheter shaft between the distal end and the proximal end; and

a dose delivery lumen extending between the inflatable balloon and the proximal end of the catheter shaft; and

a vent system comprising:

one or more vents positioned along an outer surface of the inflatable balloon; and

one or more vent lumens extending between the proximal end of the catheter shaft and the one or more vents.

57-79. (canceled)

80. (currently amended) A method of providing brachytherapy to a target tissue region of a breast ~~[[body]]~~, the method comprising:

simultaneously advancing multiple catheters into the ~~[[a]]~~ target tissue region; and

delivering one or more radiation sources through at least one catheter of the multiple catheters.

81-85. (canceled)

86. (new) A system for delivering brachytherapy to a target tissue region within a breast, comprising:

at least one elongate tubular member comprising proximal and distal ends and a lumen extending therebetween, the tubular member configured to be delivered along a first axis within the target tissue region; and

one or more radiation sources disposed within the lumen of the at least one elongate tubular member for delivering radiation therapy to the target tissue region along a second non-linear axis.

87. (new) The system of claim 86, wherein the at least one tubular member has a preferential direction of bending within or around the target tissue region.

88. (new) A system for delivering brachytherapy to a target tissue region within a breast, comprising:

at least one elongate tubular member comprising proximal and distal ends and a lumen extending therebetween, the at least one tubular member being advanceable through the breast tissue in a straight configuration and deployable to a curved configuration within the breast for delivery of radiation to the target tissue region.

89. (new) The system of claim 88, wherein the delivery system is a catheter assembly comprising:

a first catheter member; and

a second catheter member positionable within the first catheter member, the second catheter member operable to extend outwardly from an opening at or near a distal end of the first catheter member such that an axis of the second catheter member intersects an axis of the first catheter member.

90. (new) The system of claim 88, wherein the lumen of the elongate tubular member comprises a lumen configured for receiving a radioactive source and a support member.

91. (new) The system of claim 88, wherein the lumen of the elongate tubular member comprises a first lumen for receiving a radioactive source, and a second lumen for receiving a support member.

92. (new) A system for delivering brachytherapy to a target tissue region of the breast, comprising:

at least one elongate tubular member comprising proximal and distal ends and a lumen extending therebetween, the tubular member configured to be delivered along a first axis within the target tissue region;

one or more radiation sources disposed within the lumen of the tubular member for delivering radiation therapy to the target tissue region along a second non-linear axis; and
a support member provided adjacent the one or more radiation sources.

93. (new) The system of claim 92, wherein the support member comprises a metallic strip.

94. (new) The system of claim 93, wherein the strip comprises at least one of a superelastic alloy or stainless steel.

95. (new) The system of claim 92, wherein the support member is enclosed within the at least one tubular member.

96. (new) The system of claim 95, wherein the at least one tubular member comprises heat shrink tubing.

97. (new) The system of claim 92, wherein the support member has curvature in its relaxed state.

98. (new) The system of claim 92, wherein the support member is sufficiently flexible to permit curved implantation.

99. (new) The system of claim 92, wherein the lumen of the at least one tubular member comprises a first lumen for receiving the one or more radiation sources therein, and the at least one tubular member comprises a second lumen containing the support member.

100. (new) The system of claim 92, wherein the support member comprises an attenuating or shielding element such that the at least one tubular member comprises a radiotransparent portion that is not shielded by the element, and a radioabsorptive portion shielded by the element.

101. (new) The system of claim 92, wherein the one or more radiation sources comprise a plurality of radioactive seeds spaced apart along the tubular member.

102. (new) The system of claim 101, wherein the plurality of radioactive seeds are fixed to the tubular member.

103. (new) The system of claim 92, wherein the proximal end of the at least one tubular member comprises a tail portion for manipulating the at least one tubular member.

104. (new) The system of claim 92, further comprising a radioabsorptive portion positioned along a circumferential portion of the therapy delivery portion for reducing radiation exposure along a desired radial direction from the radiation source.

105. (new) The system of claim 92, further comprising a plurality of additional elongate tubular members, each comprising proximal and distal ends, a lumen extending therebetween for receiving one or more radiation sources, and configured to be implanted along a non-linear axis within the target tissue region.

106. (new) The system of claim 105, further comprising means for delivering the plurality of additional elongate therapy devices.

107. (new) A system for delivering brachytherapy to a target tissue region within a breast, the system comprising a plurality of elongate therapy devices, each comprising a therapy delivery portion advanceable through tissue in a straight configuration and deployable to a curved configuration within the breast for delivery of radiation to the target tissue region.

108. (new) The system of claim 107, wherein each therapy delivery portion is configured in the curved configuration to provide conformance of the delivery portion to a shape of the target tissue region to be irradiated.

109. (new) The system of claim 107, further comprising means for delivering the plurality of elongate therapy devices through tissue to the target tissue region.

110. (new) The system of claim 109, wherein the means for delivering the plurality of elongate therapy devices comprises a plurality of tubular members for receiving respective therapy devices therethrough.

111. (new) The system of claim 107, wherein the plurality of tubular members are configured to be delivered into the target tissue region in a two-dimensional array.

112. (new) The system of claim 107, further comprising means for simultaneously delivering the plurality of elongate therapy devices through tissue to the target tissue region with the therapy delivery portions in the straight configuration.

113. (new) The system of claim 107, wherein each therapy delivery portion comprises one or more radiation sources for delivering radiation to tissue adjacent the therapy delivery portion.

114. (new) The system of claim 107, wherein the one or more radiation sources comprise a plurality of radioactive seeds spaced apart along the therapy delivery portion.

115. (new) The system of claim 107, wherein the plurality of radioactive seeds are fixed to the therapy delivery portion.

116. (new) A method for brachytherapy treatment of a target tissue region within a breast using a therapy device comprising a therapy delivery portion and a tail portion, comprising:

advancing the therapy delivery portion of the therapy device through tissue in a straight configuration;

deploying the therapy delivery portion within or around the target tissue region in a curved configuration; and

delivering radiation therapy to the target tissue region with the therapy delivery portion in accordance with a predefined therapy profile.

117. The method of claim 116, further comprising removing the therapy device from the target tissue region after delivering radiation therapy.

118. (new) The method of claim 116, wherein advancing the therapy delivery portion comprises:

introducing a tubular member through tissue to a target tissue region;

advancing the therapy delivery portion of the therapy device through the tubular member.

119. (new) The method of claim 116, wherein a plurality of therapy delivery portions are placed at the target tissue region in curved configurations.

120. (new) The method of claim 119, wherein the plurality of therapy delivery portions are placed at the target tissue region to provide conformance to the shape of the target tissue region.

121. (new) The method of claim 116, wherein the therapy device is removed from the target tissue region using the tail portion of the therapy device.

122. (new) The method of claim 116, wherein the target tissue region comprises a tumor or lesion.

123. (new) The method of claim 116, wherein the target tissue region comprises a cavity created by tumor excision.

124. (new) The method of claim 116, wherein the target tissue region comprises surrounding tissue associated with a lumpectomy cavity of a breast.

125. (new) A method for brachytherapy treatment of breast tissue, comprising:
surgically creating a cavity in a target tissue region of a breast;
introducing a plurality of tubular members through tissue to the target tissue region;
advancing a plurality of radiation therapy devices through respective tubular members to the target tissue region;
deploying therapy delivery portions of the radiation therapy devices at the target tissue region;
removing the tubular members while leaving the therapy delivery portions at the target tissue region; and
delivering radiation therapy to the target tissue region with the therapy delivery portions in accordance with a predefined therapy profile.

126. (new) The method of claim 125, wherein the radiation therapy devices comprise low dose radiation (LDR) seeds.

127. (new) A method for brachytherapy treatment of breast tissue, comprising:

surgically creating a cavity in a target tissue region of a breast;

introducing one or more tubular members through tissue and positioning at least one tubular member at or near the cavity;

deploying a therapy delivery portion of a therapy device within or around the target tissue region wherein the therapy delivery portion is advanced through a respective tubular member in a straight configuration and deployed in a curved configuration within or around the target tissue region; and

delivering radiation therapy through the respective tubular members to the target tissue region with the therapy delivery portions.

128. (new) The method of claim 127, further comprising removing the therapy delivery portions from the breast.

129. (new) The method of claim 127, wherein the therapy devices comprise tail portions extending from the therapy delivery portions, the method further comprising removing the therapy devices from the target tissue region after delivering radiation therapy.

130. (new) The method of claim 127, wherein the target tissue region comprises a cavity created by tumor excision.

131. (new) The method of claim 127, wherein the target tissue region comprises the surrounding tissue associated with a lumpectomy cavity of a breast.

132. (new) The method of claim 127, wherein the therapy delivery portions remain at the target tissue region for an hour or more.

133. (new) The method of claim 127, wherein the plurality of tubular members comprise a plurality of needles.

134. (new) The method of claim 127, wherein delivering radiation therapy comprises delivering one or more radiation sources through the therapy delivery portions, the one or more radiation sources comprising a high dose radiation (HDR) source or a low dose radiation (LDR) source.

135. (new) A method for brachytherapy treatment of breast tissue, comprising:
introducing a plurality of tubular members through tissue to a target tissue region within a breast;
advancing a plurality of low dose radiation (LDR) therapy devices through respective tubular members to the target tissue region;
deploying therapy delivery portions of the therapy devices at the target tissue region;
removing the tubular members while leaving the therapy delivery portions at the target tissue region; and
delivering radiation therapy to the target tissue region with the therapy delivery portions.

136. (new) The method of claim 135, further comprising creating a cavity in the target tissue region before introducing the plurality of tubular members.

137. (new) A system for delivering radiation therapy to the target tissue region within a breast, the system comprising one or more therapy delivery elements, each therapy delivery element comprising a tubular structure capable of containing a radioactive source, with one or more of the therapy delivery elements configured to assume a non-linear pathway within or around the target tissue region.

138. (new) The system of claim 137, wherein one or more of the therapy delivery elements are configured to circumferentially contact tissue surrounding a lumpectomy cavity.

139. (new) The system of claim 137, wherein each therapy delivery element curves within or around the target tissue region.

140. (new) The system of claim 137, wherein each therapy delivery element has a predetermined, preferential plane of bending.

141. (new) The system of claim 140, wherein each therapy delivery element is supported by a support member.

142. (new) The system of claim 141, wherein the support member comprises a metallic strip.

143. (new) The system of claim 142, wherein the metallic strip comprises a superelastic alloy or stainless steel.

144. (new) The system of claim 141, wherein the support member is encased within a tubular casing.

145. (new) The system of claim 144, wherein the tubular casing comprises heat shrink tubing.

146. (new) The system of claim 137, wherein each therapy delivery element is constructed to cause a predetermined preferential plane of bending of the delivery element.

147. (new) The system of claim 137, wherein the one or more therapy delivery elements assume a repeating pattern of curvilinear pathways within or around the target tissue region when deployed at the target tissue region.

148. (new) The system of claim 147, wherein the one or more therapy delivery elements curve within or around the target tissue region.

149. (new) A system for delivering radiation therapy to a target tissue region within a breast, comprising:

at least one therapy delivery element comprising a tubular member, the tubular member constructed to cause bending in a predetermined, preferred plane of bending to provide conformance of the at least one therapy delivery element to the target region of the lumpectomy cavity to be irradiated; and

one or more radiation sources carried by the tubular member.

150. (new) The system of claim 149, wherein the therapy delivery element is constructed to curve within or around the target tissue region.

151. (new) The system of claim 149, further comprising a support member extending along the tubular member to cause bending in a preferred direction.

152. (new) The system of claim 151, wherein the support member comprises a metallic strip.

153. (new) The system of claim 152, wherein the metallic strip comprises a superelastic alloy or stainless steel.

154. (new) The system of claim 151, wherein the support member is encased within the tubular member.

155. (new) The system of claim 151, wherein the tubular member comprises a first lumen for receiving the one or more radiation sources and a second lumen containing the support member.

156. (new) The system of claim 149, wherein the tubular member comprises heat shrink tubing.

157. (new) The system of claim 149, wherein the therapy delivery element assumes a repeating pattern of curvilinear pathways within or around the target tissue region when deployed at the target tissue region.

158. (new) The system of claim 157, wherein the therapy delivery element curves within or around the target tissue region.

159. (new) A method for breast cancer treatment, comprising:
delivering a brachytherapy source into a breast of a patient; and
applying a garment comprising radioactive shielding to attenuate emission of radiation from the brachytherapy source to regions external to the patient.

160. (new) A system for simultaneously implanting a plurality of brachytherapy devices into a target tissue region of a breast, the system comprising:

a predetermined array comprising a plurality of delivery catheters arranged in a relationship to one another; and

one or more radiation sources deliverable within the delivery catheters.

161. (new) The system of claim 160, where the predetermined array is a circular array of delivery catheters.

162. (new) The system of claim 160, where the delivery catheters are arranged in a fixed relationship to one another.

163. (new) The system of claim 160, further comprising one or more radioactive sources advanceable into the plurality of catheters.

164. (new) The system of claim 163, wherein the one or more radioactive sources comprise a plurality of radioactive seeds.

165. (new) The system of claim 160, wherein the plurality of catheters are advanceable through the breast tissue in a straightened configuration and deployable within or around the target tissue region in a curved configuration.

166. (new) The system of claim 160, wherein at least one or more of the plurality of catheters further comprises a support member.

167. (new) The system of claim 160, wherein the support member is enclosed within the at least one or more of the plurality of catheters.

168. (new) The system of claim 160, wherein the plurality of catheters comprise a plurality of needles.

169. (new) A method of providing brachytherapy to a target tissue region of a body, the method comprising:

providing a removably implantable breast brachytherapy treatment system comprising multiple flexible tail portions and therapy delivery portions;

simultaneously locating the therapy delivery portions at a specified position within the target tissue region, wherein the tail portions protrude outside the body; and

delivering radioactive sources through the breast brachytherapy treatment system.

170. (new) The method of claim 169, further comprising removing the breast brachytherapy treatment system from the target tissue region after delivering radiation therapy.

171. (new) The method of claim 170, wherein the breast brachytherapy treatment system is removed from the target tissue region using the tail portions.

172. (new) The method of claim 169, wherein the breast brachytherapy treatment system is placed at the target tissue region in a curved configuration.

174. (new) The method of claim 169, wherein the target tissue region comprises a tumor or lesion.

175. (new) The method of claim 169, wherein the target tissue region comprises a cavity created by tumor excision.

176. (new) The method of claim 169, wherein the target tissue region comprises surrounding tissue associated with a lumpectomy cavity of a breast.

177. (new) A method for treating breast tissue, comprising:
delivering a plurality of low dose radiation (LDR) sources into the breast so that the sources are indwelling in an out-patient setting; and
removing the LDR sources from the breast after a predetermined time.

178. (new) The method of claim 177, wherein the LDR sources comprise seeds.

179. (new) The system of claim 88, wherein the lumen of the elongate tubular member comprises a lumen configured for receiving a radioactive source.

180. (new) The system of claim 88, further comprising a radiation source receivable
in the lumen.